

MUCINEX JUNIOR COLD AND FLU- acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride tablet, coated
RB Health (US)LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Mucinex® Junior
Cold and Flu

Drug Facts

<i>Active ingredients (in each caplet)</i>	<i>Purposes</i>
Acetaminophen 162.5 mg	Pain reliever/fever reducer
Dextromethorphan HBr 5 mg	Cough suppressant
Guaifenesin 100 mg	Expectorant
Phenylephrine HCl 2.5 mg	Nasal decongestant

Uses

- temporarily relieves these common cold and flu symptoms:
 - cough
 - nasal congestion
 - headache
 - sore throat
 - minor aches and pains
 - sinus congestion and pressure
- temporarily reduces fever
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

Warnings

Liver warning

This product contains acetaminophen. Severe liver damage may occur if your child takes:

- more than 5 doses in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen

Allergy alert

Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

Sore throat warning

If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- in a child who is taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.

Ask a doctor before use if the child has

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- persistent or chronic cough such as occurs with asthma
- cough that occurs with too much phlegm (mucus)

Ask a doctor or pharmacist before use if the child is taking the blood thinning drug warfarin

When using this product do not use more than directed (see Overdose warning)

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion, or cough gets worse or lasts more than 5 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back, or occurs with fever, rash, or headache that lasts. These could be signs of a serious condition.

Keep out of reach of children.

Overdose warning

Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical even if you do not notice any signs or symptoms.

Directions

- **this product does not contain directions or complete warnings for adult use**
- **do not give more than directed (see Overdose warning)**
- dose as follows or as directed by a doctor
- children 6 to under 12 years of age: give 2 caplets every 4 hours while symptoms last; do not give more than 5 doses in any 24-hour period
- children under 6 years of age: do not use

Other information

- Store at 20-25°C (68-77°F)

Inactive ingredients

corn starch, crospovidone, FD&C blue no. 1 aluminum lake, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, talc, titanium dioxide

Questions?

1-866-MUCINEX (1-866-682-4639) You may also report side effects to this phone number.

Dist. by: RB Health (US)

Parsippany, NJ 07054-0224

PRINCIPAL DISPLAY PANEL - 20 Caplet Blister Pack Carton

Pediatrician Recommended[†]

NDC 63824-670-20

NEW

Mucinex®

Junior

COLD & FLU

Acetaminophen 162.5 mg – Pain Reliever/Fever Reducer

Dextromethorphan HBr 5 mg – Cough Suppressant

Guaifenesin 100 mg – Expectorant

Phenylephrine HCl 2.5 mg – Nasal Decongestant

Ages

6⁺

yrs

SORE THROAT

FEVER

CHEST CONGESTION

COUGH

NASAL CONGESTION

SINUS CONGESTION

SINUS PRESSURE

HEADACHE

BODY PAIN

ALL IN

ONE*

Junior Caplet[±]

Actual Size

20 CAPLETS

DO NOT CHEW



MUCINEX JUNIOR COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63824-670
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	162.5 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg

Inactive Ingredients	
Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
CROSPOLYMER, UNDESIGNATED (UNII: 2S7830E561)	
FD&C BLUE NO. 1--ALUMINUM LAKE (UNII: J9EQ43S2JM)	
MAGNESIUM STEARATE (UNII: 70097M6B30)	
MALTO DEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNDESIGNATED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNDESIGNATED (UNII: 532B59J990)	
POLYMER, UNDESIGNATED (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
sodium starch glycolate type b potato (UNII: 27NA468985)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	BLUE	Score	no score
Shape	OVAL	Size	14mm
Flavor		Imprint Code	Mx;Jr
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824-670-20	1 in 1 CARTON	04/01/2019	
1		20 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	04/01/2019	

Labeler - RB Health (US)LLC (081049410)